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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/503,606	07/18/95	SHORT	J 331400-21
EXAMINER			

HM11/1001
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ART UNIT	PAPER NUMBER
1652	16

DATE MAILED: 10/01/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 7/13/98

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 (three) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 2, 3, and 5-11 is/are pending in the application.
Of the above, claim(s) 2, 3, 5 and 6 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 7-11 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 2, 3 and 5-11 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Art Unit: 1652

DETAILED ACTION

1. The request filed on July 13, 1998 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/503,606 is acceptable and a CPA has been established. An action on the CPA follows.

Response to Amendment

2. Applicant's amendment filed February 2, 1998 has been entered and considered. Claim 12 has been canceled. Claims 2, 3 and 5-11 remain pending. Claims 2, 3, 5 and 6 remain withdrawn from consideration as being directed to a non-elected invention as described in the election with traverse in the previous Office Action of February 7, 1997.

Specification

3. The Examiner acknowledges Applicant's amendment to the specification at page 12, line 6.

Objections/Rejections Withdrawn

4. In light of the amendment to the claim, the previous objection to claim 9 because of an informality is withdrawn.

Art Unit: 1652

5. In light of the amendment to the claim, the previous rejection of claim 9 under 35 U.S.C. 112, first paragraph, concerning new matter is withdrawn.

6. In light of claim amendments and cancellations, the previous rejection of claims 7-12 under 35 U.S.C. 102(b) as being anticipated by GibcoBRL is withdrawn.

7. In light of claim amendments and cancellations, the previous rejection of claims 7-12 under 35 U.S.C. 102(b) as being anticipated by Boehringer Mannheim is withdrawn.

Claim Rejections - 35 U.S.C. § 112

8. Claim 11 is again rejected under 35 U.S.C. 112, first paragraph, as containing subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection has been explained in the previous Office Action. Applicant's arguments, filed February 2, 1998 and repeated on July 13, 1998, will be fully addressed following this restatement of the rejection.

Claim 11 is drawn to encompass kits comprising enzymes selected based on "molecular weight, isoelectric point, amino acid content and crystal structure." Despite a review of the specification, the Examiner is unable to locate adequate literal or descriptive support for the scope of selecting enzymes based on these particular criteria. Thus there is no indication that kits

Art Unit: 1652

comprising agents selected based on such criteria were within the scope of the invention as conceived by Applicant at the time the application was filed. Accordingly, Applicants are required to cancel the new matter in the response to this Office Action.

Applicant argues that page 3, lines 5-9 describes the use of physical characteristics to classify or distinguish enzymes; that techniques to identify such physical characteristics are readily available; and that the specification need not disclose what is well known in the art.

While the Examiner generally agrees in principle with all three assertions, he notes that the basis of the rejection is with regard to subject matter in the claims that is not adequately described by the application as originally filed to support the position that the subject matter was within the scope of the invention as conceived at the time of filing. In the instant case, while the specification does generally discuss the use of physical characteristics, there is no literal or descriptive support for the particular characteristics recited in claim 11. As such, and despite the availability of techniques to identify enzymes based on such characteristics, there is inadequate support for the recitation of the particular means recited in claim 11. While Applicant's last assertion is generally true with regard to compliance with the standards for enablement, the specification still must disclose the scope of the invention as conceived at the time of filing.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1652

Claims 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite for the recitation of "uncharacterized enzymes" in claim 7 because the ability to recognize enzymes as reacting with the compounds recited in claim 8, as having specificity for structures as recited in claim 9, as producing a specific enantiomeric product in claim 10, and as being selected by the characteristics recited in claim 11 is by definition a form of enzyme characterization. As such, it is confusing as to how the claims can encompass kits comprising "uncharacterized enzymes" when the enzymes have being characterized to various extent.

The Examiner notes that claim 7 is excluded from this rejection solely due to the fact that all categories of enzymes are recited within the recited Markush grouping, thus no "characterization" need have occurred for a kit to be encompassed by that claim.

10. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for kits comprising enzymes selected based on chemical/enzymatic properties, does not reasonably provide enablement for kits comprising unpurified and uncharacterized enzymes selected by amino acid content or crystal structure. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims. Factors to be considered in determining

Art Unit: 1652

whether undue experimentation is required, are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claims, unpredictability in the art, the amount of direction or guidance presented, and the amount of experimentation necessary.

The claim is drawn to encompass kits comprising unpurified and uncharacterized enzymes selected by amino acid content or crystal structure. The art, however, realizes the need for at least purified enzymes in order to either obtain meaningful data from amino acid content or a crystal for the derivation of a structure. This is necessarily the case because any amino acid content analysis of a mixture of unpurified and uncharacterized enzymes (which is simply a mixture of heterogenous polypeptides as far as amino acid content is concerned) reveals nothing about the particular enzymes contained therein. Simply put, there is no meaningful distinction between the amino acid contents of different mixtures of unpurified and uncharacterized enzymes. Despite methods in the art to obtain amino acid content information about many mixtures of polypeptides, it is not routine in the art to obtain all such information where the expectation is that the information is meaningless as a means to distinguish one mixture from another. Thus, the skilled artisan would require guidance in order to make and use kits in a manner reasonably commensurate with the scope of the claim. Without such guidance, the experimentation left to those skilled in the art is undue.

Regarding crystal structure, it is well recognized in the art that the critical step is the need for an actual crystal from which a structure can be derived. Since it is virtually impossible to

Art Unit: 1652

obtain such a crystal from a mixture of unpurified enzymes, it would require undue experimentation to make crystals from such a mixture. Thus the skilled artisan cannot make and use kits in a manner commensurate with the scope of the claim.

Claim Rejections - 35 U.S.C. § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Barns et al.

Barns et al. teach the collection of biomass from sediment of a hot spring in Yellowstone National Park. Specifically, they teach the collection of the upper 1-10 mm of sediment and frozen on dry ice and stored at -70°C until processed (see page 1609, right column, start of Materials and Methods). Since these samples were collected because they contained uncultivated microorganisms, many if not all of which excrete enzymes, the collection of samples constitutes a "kit" in which individual samples in individual containers are encompassed by the claims. Thus Barns et al. anticipate the claims.

12. Claims 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Luksas et al.

Art Unit: 1652

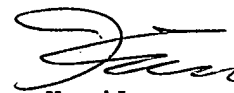
Luksas et al. teach the existence, sale and use of "Koji" culture as a starter culture for the production of soy sauce as well as the fact that "Koji culture produces growth mainly of largely unidentified molds, yeasts and bacteria in the mixture of soybeans and wheat" (see column 2, line 25 to column 3, line 7). Since "Koji" contains microorganisms, many if not all of which excrete enzymes, any package of "Koji" constitutes a container comprising enzymes and any collection of packages would be a "kit" encompassed by the claims. Thus Luksas et al. anticipate the claims.

13. Any inquiry concerning this communication or earlier communications should be directed to Kawai Lau whose telephone number is 703-308-4209. The examiner can normally be reached Monday-Friday from 7 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at 703-308-4216. The fax phone number for Official Papers to Technology Center 1600 is (703) 305-3014 or (703) 308-4242. The fax phone number for Unofficial Papers to the Examiner is (703) 305-7401.

* Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is 703-308-0196.

Kawai Lau, Ph.D.
Group 1650
September 27, 1998



Kawai Lau
Patent Examiner
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